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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/156,952	09/18/1998	ROY A. OSTGAARD	CYM-025	1770

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

23

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/156,952

Applicant(s)

OSTGAARD ET AL.

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8,10,12-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
3. Claim 1-8,10,12-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1, disclose the anti-rotation lug as comprising a planar, longitudinally disposed surface extending radially outwardly, from the body outer surface. The term "planar" is not disclosed within the instant specification. Applicant relies on Figs. 1-2, 4-5 for support, however, the specification does define the lugs as approximately 1/8 of an inch in height and 1/16 of an inch in width, see page 12, lines 23-26. There is *no mention* of an outwardly extending, "planar" or flat portion. Nor are there any dimensions for such a limitation disclosed within the instant specification.

Additionally, Applicant has included the anti-rotation lug having a longitudinally disposed surface comprising a *lowermost edge* that is substantially perpendicular to said body

outer surface into claim 1. There is no mention of the *lowermost edge* of the lug within the instant specification. Applicant relies on Figure 5 for support. However, as stated on page 14 of the specification, "[O]f course, other suitable materials, dimensions, and **configurations** for the body, the cap, the ribs, the **lugs**, the fluid level indicia, and other features of the sample vial will be apparent to those skilled in the art, those being provided as **example only**." The addition of the specific limitations describing the lug appears to be an attempt to carve out subject matter discovered in the prior art violates the description requirement of 35 USC 112 on the basis of lack of enablement and lack of description. These limitations recited in claim 1, did not appear in specification or claims as originally filed and therefore introduce new concepts into the disclosure.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Floyd (UPS 4,904,450).

Floyd teaches a vessel body comprising an outer 11 and inner casement 20, an open end 21, a closed end and a plurality of anti-rotation lugs 13 about the outer surface of the outer casement surface (Fig. 2). Wherein the anti-rotation lug comprises a planar, longitudinally disposed surface extending radially outwardly from the body outer surface. The planar surface of the plurality of anti-rotation lugs is accessible when the cap is engaged with the body. Moreover,

the lugs have a longitudinally disposed surface comprising a lowermost edge that is substantially perpendicular to the body outer surface (Fig. 4). Additionally, the vessel having a cap 14 with a torque pattern formed on the outer surface. The torque pattern comprising a plurality of radially disposed ribs 17. Moreover, Floyd discloses a seal surrounding the lower part of the cap 25, 26, 27, 30 which seals against fluid and pressure flow between the cap and the body (column 5, lines 9-15, Fig. 2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-8, 10, 12-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Maggio (USP 4,859,610) or Babson (USP 4,639,242).

Moore teaches a sample vial for use in an automated test apparatus comprising a body with an outer surface, an open end, a closed end, a cap 34 releasably engagable with the body,

the cap comprising an outer surface and a torque pattern (Fig. 1 & 3) on the cap outer surface, the torque pattern comprising a plurality of radially disposed ribs 64, and seals 54, 98 disposed between the body and the cap so as to be capable of forming a substantially fluid-tight seal therebetween. Moore teaches a first alignment marker 110 on the body on the cap and a second alignment marker 108 on the body (column 7, lines 24-40). Moore teaches a cap comprising first screw threads 62 (Fig. 4) and a second mating screw thread 80 on the body (Fig. 1). Moore teaches sample fluid level indicia 108 comprising an upper fill line and a lower fill line on the outer surface of the vial body (Fig. 1). Moore does not teach the use of at least one anti-rotation lug about the body outer surface.

Maggio teaches an incubation device which includes a vessel 1 for homogenizing the sample composition. The vessel comprising a body with an outer surface, an open end, a closed end, a cap 14 releasably engagable with the body, and a seal 18 disposed between the body for sealing the cap to the vessel so as to enclose noxious or hazardous material with the vessel. Moreover, Maggio discloses the use of a plurality of planar lugs 19 outside the vessel to help the user to maintain a grip on the vessel with one hand while rotating the cap with the other. The lugs 19 comprising a planar, longitudinally disposed surface. Moreover, the longitudinally disposed surface comprises a lowermost edge that is substantially perpendicular to the body outer surface (column 6, lines 3-41, Figs. 1-3, 9-12). Note: the seal is defined within the instant specification as a compliant sealing flap molded in the cap 14 or a separate seal 24, see page 9, lines 22-23.

Similarly, Babson does teach the use of a plurality of planar, outwardly extending anti-rotation lugs 31 about the container body's outer surface which are accessible when the cap 41 is

attached to the container (column 3, lines 38-59, Figs. 4-5). Moreover, Babson teaches the containers of the present invention are conveyed on a continuous track through a series of processing stations. At one such station, the lugs react against a tangential stream of fluid provided by a proximate structure to cause the container to spin about its longitudinal axis.

Babson discloses the claimed invention except for the longitudinal surface of the lugs having a lowermost edge that is substantially perpendicular to the body outer surface. It would have been an obvious matter of design choice to have made the lowermost edge of the lugs perpendicular to the container body, since the specification has not disclosed that such a shape solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with lug having a lowermost beveled edge.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the sample vial of Moore the lugs as taught by Maggio or Babson, in order to provide a cost effective means to mix or spin the contents of the vessel.

Moore does not explicitly teach the use of the body and cap made from polypropylene, however would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the body and cap from an inert material, such as polypropylene, in order to ensure that the sample inside the vial will not react with the container or cap. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Moore teaches a fluid-tight seal formed between the body and the cap (column 6, lines 41-61). However, Moore does not disclose the range of torque between 5 and 50 inch-pound of

torque applied to the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in the invention of Moore the range of torque between 5 and 50 inch-pound of torque applied to the cap in order to ensure the cap and vial are properly sealed and prevent the leakage of a sample or air from the vial. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Maggio (USP 4,859,610) or Babson (USP 4,639,242), as applied to claim 23 above, and further in view of Neeley *et al* (USP 5,164,575).

Moore, Maggio and Babson as previously discussed, does not teach a sample indicia comprising a bar code. However, such a means for identifying kinds of sample vials is considered conventional and usually required in the automatic analyzing art, see Neeley *et al*. Neeley *et al* teaches a sample indicia comprising a bar codes 7 & 51 (column 6, lines 46-68, Figs 4-5 & 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the modified apparatus of Moore, a bar code on the sample vial, as taught by Neeley *et al*, in order to identify the sample and make sure the proper sample is matched up with the patient (columns 2-3).

Response to Arguments

10. Applicant's arguments filed January 09, 2002 have been fully considered but they are not persuasive.

Applicant argues that the lugs 15 (sic.13) of Floyd (USP 4,904,450) are generally semi-cylindrical projections from the casement 11. Examiner believes that the lugs 13 are indeed "planar and longitudinally disposed". Since, Applicant has not defined or disclosed the specific limitation of "planar" in the specification, the term "planar" has been given the broadest reasonable interpretation. Additionally, "planar" is clearly defined and accepted within the art to mean having a two-dimensional characteristic, i.e. length and width. Clearly, Floyd does have lugs which have a length and width dimension. The specification defines the lugs as approximately 1/8 of an inch in height and 1/16 of an inch in width, see page 12, lines 23-26. No mention of a planar or flat portion or any such dimensions are disclosed. Therefore, the rejection is maintained.

In response to the previous rejection of claims 1-8, 10, 12-23 and 25-26 under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Babson (USP 4,639,242), Applicant argues that Babson vanes (lugs) 31 are concerned with the problem of "promoting" rotation, while Applicants' anti-rotation lugs 18 are concerned with the problem of preventing rotation. Examiner points to the specification which disclose the step wherein after the cap has been tightened in the sample vial tray forming a bore 52 with the six ramps which abuts one of the body lugs 18, the vial transfer assembly may grasp the capped vial and remove the vial from the bore and deposit it into the a bore 62 formed with a vial sleeve 64, such as depicted in Fig. 7B. Once in the bore 62 with the lugs 18 is disposed in the slots 66, the sleeve may be **rotated** in one or both directions to disperse the cells in the preservative solution prior to uncapping the vial 10. Therefore, the lugs also "promote" rotation of the contents of the vial, see paragraph bridging pages 13 to 14.

Additionally, Applicant argue that Babson includes V-grooves 32 that would interfere with the proper sealing action between the smooth mating surfaces as disclosed by the Moore cap structure. Applicants' arguments are not germane to the issue since Babson is relied upon for the teaching of the lugs 31, not the cap structure. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. No claims allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Kathryn Bex whose telephone number is (703) 306-5697.

Art Unit: 1743

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


P. Kathryn Bex
Patent Examiner
AU 1743
2/6/02


Jill Warden
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